Amendments to the Drawings

The attached replacement sheet(s) of drawings replace(s) the sheets with the corresponding figures. The replacement sheets include the following changes:

In Fig. 1, a locator 300, positioning system 310 and surgical (IGS) workstation 320 have been added.

Remarks

The Examiner's analysis and remarks set forth in the Office Action are noted with appreciation. Reconsideration of the application is requested in view of the foregoing amendments and the following remarks. The various parts of the Office Action (and other matters, if any) are discussed below under appropriate headings.

Drawings

The drawings have been objected to for not mentioning reference number 130 in the specification. To remedy this oversight, paragraph [0019] has been amended to include reference numeral 130 that identifies the distal end of the stylet.

The drawings also have been objected to for not showing certain features of claims 9-11. This oversight has been remedied by amending Fig. 1 to include a diagrammatic illustration of the "locator", "positioning system" and "image-guided workstation".

In view of the foregoing, withdrawal of the drawing objections is requested.

Claim Objections

The Examiner kindly pointed out a couple of grammatical errors in claims 6 and 20. These errors have been corrected, as has a grammatical error in claim 21.

Claim Rejections - 35 USC § 102 and § 103

The claims have been rejected as being anticipated by or unpatentable over Sirimanne (US 6,488,662), Maginot et al. (US 6,743,218), Clayton et al. (US 6,434,507), Hogan (US 5,137,515) and/or Shahbabian (US 4,312,353). Withdrawal of the art rejections is respectfully requested.

Claims 1 and 16

Claim 1 was rejected as being anticipated by Sirimanne. Sirimanne discloses a percutaneous catheter assembly comprising generally three components: a catheter housing, an end cap for closing off a proximal end of the catheter housing during insertion, and a dilator having an outer diameter substantially the same size as the inner diameter of the smallest section of the catheter housing [Abstract]. Such

assembly is used to establish a large fluid flow connection percutaneously to an artery or vein without either an introducer sheath or a guiding catheter [column 3, lines 7-11]. Consequently, both the catheter housing and dilator necessarily must be flexible for accommodating the curvilinear path of an artery or vein in the body of the patient on whom a procedure is being performed.

With that in mind, claim 1 has been amended to recite a system comprising a hollow rigid tube when compared to a tube that must be sufficiently flexible to follow the path of an artery or vein. Consequently, a system as set forth in amended claim 1 is not disclosed by Sirimanne. Moreover, the skilled person would not have been motivated to make the dilator of Sirimanne rigid as then it would be unsuitable for its intended purpose, i.e., passage through an artery or vein. It is axiomatic that none of the other references applied by the Examiner would suggest making the dilator of Sirimanne rigid since this would destroy the intended functionality of the dilator.

For at least the foregoing reason, withdrawal of the rejection of claim 1 is respectfully requested. While claims 2-15 which depend from claim 1 recite still further features, they need not be discussed because of the above mentioned deficiency of Sirimanne vis-a-vis claim 1.

The above discussion of Sirimanne is also applicable to amended claim 16 and claim 17 which depends therefrom.

Claim 18

Claim 18 was rejected as being unpatentable over Sirimanne in view of Shahbabian. The rejection, however, is believed improper at least for the reason that neither Sirimanne nor Shahbabian disclose a method as recited in claim 18, where a step of withdrawing a stylet from a catheter includes releasing into the lumen of the catheter fluid from the stylet that had been loaded into the stylet, to avoid air from occupying the lumen of the catheter upon withdrawal of the stylet. The Examiner's remarks do not appear to address this significant difference between the methodology of Sirimanne and that set forth in claim 18.

Regarding the release of fluid from the dilator of Sirimanne, the Examiner refers to column 8, lines 56-64. The noted passage forms part of the following description extracted from Sirimanne:

> The invention also comprises a method of operation of the catheter assembly 10. The method comprises penetrating the arterial site with a standard cannulation procedure, such as the Seldinger technique described in part above, so as to permit a guide wire to be inserted in the blood vessel (not shown). The cap 18 is placed within the proximal section 26 of the catheter housing 12. The dilator 20 is then placed within the catheter housing 12 through the cap 18 so that the distal end 56 of the dilator 20 extends beyond the distal tip 32 of the catheter housing. Saline is flushed through the hemostasis valve 58 and out through the distal end 56 to flush the catheter assembly 10 of any air that would be detrimental to a patient. The catheter assembly 10 is then placed over the guide wire and inserted through the patient and into the blood vessel. Radiopaque contrast is then injected through the hemostasis valve 58 and out through the first set of openings 68 in the distal end 56 of the dilator 20 to permit detection of the distal end 56 as the catheter assembly 10 is being: advanced through the patient. The radiopaque contrast also exits the second set of holes 78 in the dilator 20 and the perforations 36 of the catheter housing 12 so as to permit detection of the location of the distal end 14 of the catheter housing.
>
> Once the catheter assembly 10 is advanced to the desired point within the blood vessel, the guide wire is removed. Then the dilator 20 is retracted from the catheter housing 12, leaving the cap 18 in place. The cap 18 prevents backflow of the blood through the proximate end 16 of the housing 12 during removal of the dilator 20. When the distal end 56 of the dilator 20 is within the proximal section 26 of the catheter housing 12, a hemostat (not shown) may be used to clamp the catheter housing so as to prevent the flow of blood out of the proximal end 16 of the catheter housing. At that point, the cap 18 may be removed from the catheter housing 12 and a delivery line attached to the proximal end 16 of the catheter housing for aspiration or infusion.

[column 8, line 42 to column 9, line 10]. Accordingly, radioopaque contrast agent is injected from the dilator to permit detection of the distal end of the catheter as the catheter is being advanced through the patient. Nothing is said, however, about withdrawing the radiopaque contrast (or any other fluid) from the dilator as the dilator is removed. Instead, Sirimanne states the cap is left in place to prevent backflow of blood. From this it can be gathered that instead of any fluid from the dilator into the catheter, blood is allowed to flow into the catheter.

For at least the foregoing reason, the rejection of claim 18 should be withdrawn. The secondary reference does not overcome the noted fundamental defect of

Sirimanne, but instead was cited for other reasons that need not be addressed in view of the shortcomings of Sirimanne.

New Claims

New claims 22 and 23 depend from claim 18 and therefore are submitted as being allowable for at least the same reasons.

New claim 24 recites a system comprising a flexible tubular infusion catheter including a proximal end and a distal end and a lumen extending therebetween; and hollow stylet means insertable into the lumen of the catheter for guiding the catheter through tissue to a target location and for enabling the catheter to be tracked by a positioning system coupled to an image-guided workstation when one or more locators are attached to at least one of the catheter and hollow stylet means.

As above indicated, the catheter housing and dilator of Sirimanne must be sufficiently flexible for passage through an artery or vein. Consequently, radioopaque contrast is used is injected from the end of the dilator to permit detection of the end of the catheter assembly. Because of such flexibility, the catheter assembly of Sirimanne is not suitable for use with one or more locators that can be attached to one of the catheter and hollow stylet and tracked by a positioning system coupled to an image-guided workstation. Consequently, Sirimanne neither discloses nor suggests the recited hollow stylet means.

The "means plus function" language is being used to distinguish applicants' hollow stylet from the dilator of Sirimanne. As noted by the Examiner, the dilator of Sirimanne may be made of a material somewhat stiffer than the catheter housing. This is for the purpose of enabling the dilator to be sufficiently stiff to withstand axial forces applied at the proximal end of the assembly. While axially stiff, the dilator must still have sufficient lateral flexibility to course through an artery or vein. It is the artery or vein that guides the assembly, and thus the need for injection of radioopaque contrast for locating the end of the assembly.

In contrast, the hollow stylet means of claim 24 has sufficient stiffness for guiding the catheter through tissue to a target location and for enabling the catheter to be tracked by a positioning system coupled to an image-guided workstation when one or more locators are attached to at least one of the catheter and hollow stylet means. Accordingly, the hollow stylet means must have sufficient stiffness to maintain a known

positional relationship between the distal end thereof and the proximal end thereof where one or more locators may be attached to the catheter and/or hollow stylet means.

Conclusion

In view of the foregoing, request is made for timely issuance of a notice of allowance.

Respectfully submitted,

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CERTIFICATE OF MAILING (37 CFR 1.8a)

I hereby certify that this paper (along with any paper or thing referred to as being attached or enclosed) is being deposited with the United States Postal Service on the date shown below with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Date: May 30, 2006

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Jennifer A. Moore

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